with Ambien and Ambien CR could positively influence and treat the primary underlying mental illnesses suffered by the patient. This was above and separate from off-label marketing of Ambien and Ambien CR for mere co-prescription with other medications and treatments to prevent potential sleep disturbances without regard to whether or not clinically significant insomnia had been diagnosed.

143. The motivation for Sanofi to misbrand is obvious. Clinical depression with or without concomitant treatment with SSRI drugs and other psychiatric illnesses, including anxiety and mood disorders, are among the most common mental health problems worldwide and in the United States and represent an enormous market that Sanofi successfully accessed through its illegal marketing strategies. However, in order to effectively penetrate this lucrative market, Sanofi understood that it needed to first devise and implement deceptive representations of scientific and clinical facts so that their marketing efforts would appear to provide sound medical advice within the bounds of the FDA-approved package labeling.

144. Sanofi based its deceitful scientific assertions on the faulty syllogism that if mental disorders are a leading cause of insomnia then it is medically and scientifically sound to promote the assertion that insomnia causes mental disorders. The scientific studies Sanofi set forth as the basis for the falsehood fail to support this assertion and also ignore the fact that excessive sleep (hypersomnia) is also linked with psychiatric illness diagnoses. By baselessly asserting that treatment with Ambien and Ambien CR could prevent future episodes of both insomnia and the associated mental disorder, Sanofi sought to portray its drugs as a form of vaccine against a myriad of psychiatric illnesses – an indication never approved by the FDA and having no basis in any medical compendia such as DRUGDEX, the American Hospital Formulary Service Drug Information or the United States Pharmacopeia-Drug Information.

2. Sanofi's Misbranding of Ambien and Ambien CR as Having Efficacy in the Treatment of Clinical Depression Ignored Concerns About Patient Safety

145. Both Ambien and Ambien CR are identified as central nervous system depressants in the FDA-approved package labeling and in well-respected medical compendia such as DRUGDEX, the American Hospital Formulary Service Drug Information or the United States Pharmacopeia-Drug Information. All of these publications warn against the use of zolpidem and central nervous system depressants in treating patients with clinical depression.

146. Despite these safety concerns, Sanofi's sales teams were handsomely rewarded for persuading its target audiences to ignore any of these patient safety concerns in seeking to induce the automatic co-prescription of Ambien and/or Ambien CR in patients with a number of psychiatric disorders. In direct contravention of the FDA-approved package labeling, Sanofi's sales efforts sought to convince physicians and health care providers that they were not doing everything they could to help their patients unless they assumed that insomnia would emerge in numerous off-label conditions and that Ambien and Ambien CR could affirmatively ward off the onset of those conditions. Sanofi even created a Psychiatry sales force of about 150 representatives to carry out these illegal promotions. This sales force did nothing else but detail psychiatrists about the use of Ambien and/or Ambien CR in psychiatric conditions.

3. Sanofi S.A. Also Misbranded Ambien and Ambien CR By Seeking to Disguise the Benzodiazepine Nature of Zolpidem

147. In seeking to distinguish Ambien and Ambien CR from other benzodiazepine drugs such as Valium, Klonopin, Xanax, and Librium, Sanofi S.A. sought to portray the active ingredient in Ambien and Ambien CR as being different in nature than benzodiazepine. The motivation for this misbranding was to avoid the negative associations with "benzo" drugs such as abuse, dependency, tolerance, withdrawal and lack of rebound effect.

148. This misbranding, however, is specifically contradicted by studies comparing benzodiazepines like Valium, Klonopin, Xanax and Librium with non-benzodiazepines with similar effects like zolpidem. Studies like the Benzodiazepine Equivalents Table specifically conclude that although zolpidem and its peers are chemically different from benzodiazepine, zolpidem and its peers have the same effect on the body and act by the same mechanisms. Similarly, a 2004 study states that the rates of actual abuse and dependence upon zolpidem appear to be similar to other hypnotic benzodiazepines currently listed in Schedule IV and concludes that zolpidem carries mild tolerance and mild rebound insomnia – a statement in sharp contrast to Sanofi's claim that Ambien and Ambien CR had no tolerance nor rebound characteristics.

N. Sanofi S.A. Falsely Promoted Ambien CR As Being Superior to Ambien Despite Knowing that the Two Drugs Were Essentially Identical Except that Sanofi Could Charge More for Ambien CR

149. In 2005, having illegally promoted Ambien for several years in order to maximize sales, Sanofi faced the challenge of having to market against itself with the introduction of Ambien CR. Facing the expiration of Ambien's patent, Sanofi created Ambien CR – a time release version of Ambien (Ambien is also referred to as Ambien IR, which stands for Immediate Release) in order to maintain a higher-priced prescription drug in the face of Ambien going generic.

150. Initially, Sanofi hoped to sponsor clinical trials that would distinguish Ambien CR as different and better than Ambien. However, when the results of clinical trials failed to produce these results, Sanofi made the same claims anyway and sought to bury the poor results of the clinical trials.

151. The 2006 - 2008 Strategic Brand Plan titled "Ambien to AmbienCR" ("'06 - '08

Strategic Brand Plan" or "Plan") sets forth the flaws with Ambien CR requiring illegal marketing techniques to remedy as including:

- Lack of market perception of minimal differentiation versus current Ambien
- Ambien CR is at a competitive disadvantage with certain clinical data
- Limited investment in clinical development programs to support co-morbid conditions.

152. The '05-'06 Plan also identified psychiatrist prescription growth rates as lagging behind PCPs (Primary Care Physicians) and noted a redeployment of the sales force to address this problem. The plan then articulates an aggressive plan to misbrand Ambien and Ambien CR and to make false superiority claims for Ambien CR as compared to Ambien.

1. Sanofi S.A. Tried to Differentiate from Ambien by Claiming that Only Ambien CR was approved for Sleep Maintenance As Well as Sleep Onset Even Though Sanofi Had Previously Marketed Ambien as Being Effective for Both

153. In its marketing for Ambien, Sanofi originally promoted Ambien for trouble falling asleep (sleep onset), staying asleep and waking too early (sleep maintenance). The label for Ambien speaks only to short-term treatment of insomnia. However, when Sanofi was about to release Ambien CR due to the looming expiration of Ambien's patent, Sanofi sought to convert Ambien business to Ambien CR and claimed Ambien CR was superior to Ambien because – unlike Ambien - Ambien CR was good for sleep onset and sleep maintenance. Obviously, Sanofi cannot have it both ways. Either they misbranded and made false superiority claims about Ambien being good for both sleep onset and sleep maintenance or they made false superiority claims about Ambien CR because its indication showed it accomplished exactly the same thing as Ambien. Even Sanofi reps complained, "we promoted Ambien for sleep onset and maintenance, and now you want me to go back and tell my doctors oh I lied to you about Ambien, now Ambien CR is better."

2. Sanofi S.A. Falsely Asserted that Ambien CR Was Superior to Ambien In That Patients Expressed Greater Satisfaction and Had "Better Next Mornings"

154. Throughout Sanofi's strategic brand plans like the '06-'08 Plan, Sanofi repeatedly states its intention to position Ambien CR as superior by emphasizing "the next day effects" upon all manner of non-clinically substantiated criteria ranging from a happier mood to better time management skills. In truth, a comparison of Ambien and Ambien CR labels reveals that Ambien CR patients report a higher rate of next day somnolence – an effect akin to a hangover.

155. In sales' visual aids designed by Sanofi's marketing department, repeated depictions of misleading head-to-head comparisons were made showing the false superiority of Ambien CR over Ambien. For example, a bar chart showing alleged superior results for fewer awakenings for Ambien CR patients was juxtaposed with a clinical study result showing results of Ambien CR contrasted with a placebo. The juxtaposition and bar chart conveyed the false impression that clinical studies had been done comparing Ambien CR head-to-head against Ambien. In truth, no such clinical studies had been performed in this instance. Two clinical studies conducted showed no difference between Ambien and Ambien CR, but Sanofi buried these studies

156. Another graph showed what appeared to be the head-to-head comparison of Ambien CR with Ambien to show Ambien CR's superiority at keeping patients asleep when in fact the only data shown in the chart was that of the blood plasma levels of healthy patients and self-reported results of healthy patients exposed to traffic noise simulations. Again, the juxtaposition of the data falsely portrayed clinical studies showing the superiority of Ambien CR to Ambien even though no such clinical studies had been performed.

VII. SANOFI S.A. CAUSED THE SUBMISSION OF FALSE OR FRADULENT CLAIMS TO FEDERAL AND STATE HEALTH INSURANCE PROGRAMS

157. Between at least 2002 and the present, Defendant knowingly violated federal regulatory schemes in its improper marketing of Ambien and Ambien CR. When Defendant chose to employ its system of illegal kickbacks, misbranding and off-label marketing, it knew or should have known that physicians and pharmacists would be caused to file false and fraudulent claims with the federal government when they sought state and federal reimbursement for Ambien and Ambien CR prescriptions. But for Sanofi S.A.'s actions, most, if not all, of the false claims for the prescriptions of Ambien and Ambien CR would never have been filed. Defendant benefited from all the false claims and fraudulent claims described in this complaint.

158. Defendant actively sought out the promotion of Ambien and Ambien CR to insurance programs, including Medicaid. Defendant provided each of its sales representatives with a computer program that allowed querying by zip code for insurance programs and what tier Ambien and Ambien CR fell within for particular insurance reimbursement plans. When sales representatives accompanied Speakers on visits to physicians, the sales representative would prompt a discussion about the price of the drug. The Speaker would have been instructed ahead of time to tell the targeted physician that for slightly more money the physician could have a better drug and together, the sales representative and Speaker would show how it could be reimbursed from various insurance programs, including Medicaid. Using federal and federally-supported state Medicaid funding that paid for and/or reimbursed the cost of Ambien and Ambien CR prescriptions, the patients' cost was usually zero. When Defendant's promotions used the reimbursement information and coupled it with the alleged low abuse risk reminder from the sales representatives, healthcare practitioners were eager to prescribe.

159. Medicaid claims for payment of misbranded, off-label Ambien and Ambien CR

prescriptions and/or prescriptions induced by illegal kickbacks are filed with the states by pharmacists who fill the Medicaid or other government reimbursed prescriptions. In most cases, the pharmacist will not know whether the prescription is misbranded or off-label because prescriptions are not required to state the patient's diagnosis, nor will they know if the prescription was produced by a kickback. Thus, the pharmacist will not know if the prescription is a valid one for federal or state reimbursement. Each of those invalid prescriptions, however, constitutes a false claim under the Federal False Claims Act, 31 U.S.C. § 3729 et seq. and the analogous laws of the Plaintiff States and Cities. Defendant, as the one who knowingly caused such false or fraudulent claims to be filed, is thus liable under the Federal False Claims Act as well as those analogous laws of the Plaintiff States and Cities for each and every false claim submitted.

VIII. OTHER GOVERNMENT FUNDED HEALTHCARE PROGRAMS DAMAGED BY PAYING FALSE AMBIEN AND AMBIEN CR CLAIMS

160. In addition to Medicaid, the federal government reimburses a portion of the cost of prescription drugs under several health care programs, including but not limited to Medicare, Medicare Part D, the Railroad Retirement Medicare Program, Federal Employees Health Benefit Programs, Tri-Care (formerly CHAMPUS), CHAMPVA, the Federal Employees Compensation Act Program, the Bureau of Prisons, State Legal Immigrant Assistance Grants and the Indian Health Service, the Department of Defense, the Department of Labor, and the Public Health Service Entities. As alleged below, these programs operate in similar ways to the Medicare program. For example, the VA and CHAMPUS/Tri-care operate in substantially similar ways to the Medicare and Medicaid programs, but primarily for the benefit of military veterans, their spouses (or widowed spouses) and other beneficiaries.

161. Coverage of off-label drug use under these programs is similar to coverage under

the Medicaid program. E.g., TRICARE Policy Manual 6010.47-M, Chapter 7, § 7.1 (B) (2) (March 15, 2008); CHAMPVA Policy Manual, Chapter 2, § 22.1, Art. II (A)(2) (June 6, 2008).

A. Medicare and Medicare Part D

162. Medicare is a government financed health insurance program administered by the Social Security Administration of the United States. The health insurance provided to beneficiaries of the Medicare insurance program is paid in whole or in part by the United States. Medicare was promulgated to provide payment for medical services, durable medical equipment and other related health items for individuals 65 and over. Medicare also makes payment for certain health services provided to additional classes of individual healthcare patients pursuant to federal regulation.

163. The Medicare Prescription Drug Improvement and Modernization Act of 2003 added prescription drug benefits to the Medicare program. The Medicare Prescription Drug benefit covers all drugs that are considered "covered outpatient drugs" under 42 U.S.C. § 1396r-8(k) (as described above).

164. The first stage of the Medicare program, from May 2004 through December 2005, permitted Medicare beneficiaries to enroll in a Medicare-approved drug discount card program.

165. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the MMA). Title I of the MMA created new outpatient prescription drug coverage under Medicare (Medicare Part D).

166. Medicare Part D went into effect on January 1, 2006. The Program is administered by the United States Department of Health and Human Services, Centers for Medicare and Medicaid (CMS). For "dual eligibles," defined as individuals who received prescription drug coverage under Medicaid in addition to Medicare coverage for other health

care in 2005, enrollment in Medicare Part D was compulsory. Such beneficiaries were automatically switched to Part D plans for 2006 and commenced receiving comprehensive prescription drug coverage under Medicare Part D.

167. Coverage of prescription drugs under Medicare Part D is subject to the same regulations as coverage under the Medicaid Program described above.

168. As a direct, proximate and intended result of the conduct of the Defendant, alleged herein in violation of the Federal False Claims Act and the analogous laws of the Plaintiff States and Cities, the Medicare and Medicare Part D programs have been damaged.

B. The Railroad Retirement Medicare Program

169. The Railroad Retirement Medicare program is authorized by the Railroad Retirement Act of 1974, at U.S.C.A. § 231 et seq. It is administered through the United States Railroad Retirement Board (RRB) and furnishes Medicare coverage to retired railroad employees.

170. As a direct, proximate and intended result of the conduct of the Defendant, alleged herein in violation of the Federal False Claims Act and the analogous laws of the Plaintiff States and Cities, the RRB program has been damaged.

C. Federal Employee Health Benefit Plans

171. The Federal Employees Health Benefits Program (FEHBP) is administered by the United States Office of Personnel Management (OPM) pursuant to 5 U.S.C.A § 8901 et seq. and provides health care coverage to federal employees, retirees and their dependants and survivors.

172. As a direct, proximate and intended result of the conduct of the Defendant, alleged herein in violation of the Federal False Claims Act and the analogous laws of the Plaintiff States and Cities, the FEHBP program has been damaged.

D. Tri-Care

173. The Tri-Care program, formerly, CHAMPUS, is administered by the United States Department of Defense through its component in agency, CHAMPUS, under the authority of 10 U.S.C.A. §§1701-1106. It is a health care program that provides for care in civilian facilities for members of the uniformed services and their dependents.

174. Pursuant to 38 U.S.C.A. § 8126, and the regulations based thereon, drugs furnished by drug manufactures to the Department of Defense must be furnished at the best price.

175. As a direct, proximate and intended result of the conduct of the Defendant, alleged herein in violation of the Federal False Claims Act and the analogous laws of the Plaintiff States and Cities, the Tri-Care program has been damaged.

E. The Veterans Administration

176. The Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA) is a comprehensive health care program in which the VA shares the cost of covered health care services and supplies with eligible beneficiaries. The program is administered by Health Administration Center and its offices are located in Denver, Colorado. In general, the CHAMPVA program covers most health care services and supplies that are medically and psychologically necessary.

177. Due to the similarity between CHAMPVA and the Department of Defense (DOD) Tri-Care program, the two are often mistaken for each other. CHAMPVA is a Department of Veterans Affairs program whereas Tri-Care is a regionally managed health care program for active duty and retired members of the uniformed services, their families and survivors. In some cases a veteran may appear to be eligible for both/either program on paper. However, military

retirees, or the spouse of a veteran who was killed in action, are and will always be Tri-Care beneficiaries.

178. Pursuant to 38 U.S.C.A. § 8126 and the regulations based thereon, and contracts the Veterans Administration had with manufacturers, drugs furnished to the Veterans' Administration by drug manufacturers must be furnished at the best price.

179. The VA and CHAMPUS/Tri-care operate in substantially similar ways to the Medicare and Medicaid programs, but primarily for the benefit of military veterans, their spouses (or widowed spouses) and other beneficiaries.

180. As a direct, proximate and intended result of the conduct of the Defendant, alleged herein in violation of the Federal False Claims Act and the analogous laws of the Plaintiff States and Cities, the CHAMPVA program has been damaged.

F. Indian Health Service

181. The Indian Health Service is responsible for providing comprehensive health services to more than 1,400,000 Americans. It is administered by the Department of Health and Human Services pursuant to 42 U.S.C.A. § 2008 et seq. The statute authorizes the Secretary to enter into contracts with independent providers to furnish health services to Native Americans whenever the Secretary determines that independent providers can better meet the population's need.

182. As a direct, proximate and intended result of the conduct of the Defendant, alleged herein in violation of the Federal False Claims Act and the analogous laws of the Plaintiff States and Cities, The Indian Health Service program has been damaged.

G. State Legal Immigrant Assistance Grants

183. Relators are informed, believe and based thereon allege that the United States also

furnishes funds which several States use to pay for prescription drugs pursuant to State Legal Immigrant Assistance Grants (SLIAG), 8 U.S.C.A § 1255A; 45 C.F.R. § 402.10.

184. As a direct, proximate and intended result of the conduct of the Defendant, alleged herein in violation of the federal false claims act and the analogous laws of the Plaintiff States and Cities, the SLIAG program has been damaged.

IX. CLAIMS FOR RELIEF

COUNT ONE

Violations of the Federal False Claims Act
31 U.S.C. § 3729(a)(2)(A)
Presenting or Causing to be Presented False Claims

185. Relators reallege and incorporate by reference each and every one of the foregoing paragraphs as if fully set forth herein.

186. This is a qui tam action brought by Relators and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. §3730 for Defendant's violations of 31 U.S.C. § 3729 et seq.

187. The Federal False Claims Act, 31 U.S.C. § 3729(a)(2)(A) provides:

Liability for certain acts. Any person who--

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.

188. By virtue of the above-described acts, among others, Defendant knowingly presented or caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the United States, in violation of 27 U.S.C. § 3729(a)(2)(A).

189. Those false claims include claims for reimbursement for off-label/non-medically

accepted prescriptions of Defendant's drug Ambien and Ambien CR which would not have been submitted, and thereafter paid by the United States, but for the illegal practices of Defendant described in this Complaint.

190. Plaintiff United States, unaware of the falsity of the claims that the Defendant caused doctors, pharmacies, hospitals and other health care providers to make to the United States, and in reliance on the accuracy thereof, paid said doctors, hospitals, pharmacies and other health care providers for claims that would otherwise not have been allowed. These claims – prescription drug reimbursement claims for Defendant's drug Ambien and Ambien CR – were false as that term is defined by the Federal False Claims Act in that they were ineligible for reimbursement as described herein.

191. For those claims that Defendant submitted or caused to be submitted, it was foreseeable and in fact the intended result that those claims would be submitted. Further, at all times relevant to the Complaint, Defendant acted with the requisite scienter.

192. By reason of Defendant's unlawful practices, substantial numbers of doctors, hospitals, pharmacies and other health care providers in the United States have been induced to purchase substantial quantities of Defendant's drug Ambien and Ambien CR and these practices thus provided substantial unlawful profits to Defendant.

193. By reason of these unlawful practices by Defendant, as aforesaid, doctors, hospitals, pharmacies and other health care providers have been induced to purchase Defendant's drug Ambien and Ambien CR rather than recommending less expensive drugs, procedures or treatment options for their patients.

194. The amounts of the false or fraudulent claims to the United States were material. Relator United States, being unaware of the falsity of the claims and/or statements caused to be

made by Defendant, and in reliance on the accuracy thereof, paid and continues to pay for Defendant's unlawfully induced prescriptions.

195. It is believed that as a result of Defendant's violations of 31 U.S.C. § 3729 (a)(1)(A), the United States has suffered substantial losses in an amount that exceeds hundreds of millions of dollars, and is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false claim presented or caused to be presented by Defendant.

196. Relators are private people with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to the Federal False Claims Act on behalf of themselves and the United States.

COUNT TWO

Violations of the Federal False Claims Act
31 U.S.C. § 3729(a)(2)(B)
Creation or Use of False Statements or Records Material to a False Claim

197. Relators reallege and incorporate by reference each and every one of the foregoing paragraphs as if fully set forth herein.

198. This is a qui tam action brought by Relators and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. § 3730 for Defendant's violations of 31 U.S.C. § 3729 et seq.

199. The Federal False Claims Act, 31 U.S.C. § 3729(a)(2)(B) provides:

Liability for certain acts. Any person who--

> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.

200. By virtue of the above-described acts, among others, Defendant knowingly made or used or caused to be made or used false records or statements material to false claims, and

continues to do so, in violation of 27 U.S.C. § 3729(a)(2)(B).

201. Tens of thousands of claims for reimbursement for off-label prescriptions of Defendant's drug Ambien and Ambien CR would not have been submitted, and thereafter paid by the United States, but for the illegal practices of Defendant described in this Complaint including the creation and use of false statements or records by Defendant.

202. Plaintiff United States, unaware of the falsity of the records and/or statements which the Defendant made or caused doctors, pharmacies, hospitals and other health care providers to make that were material to false claims, and in reliance on the accuracy thereof, paid said doctors, hospitals, pharmacies and other health care providers for claims that would otherwise not have been allowed. These claims – prescription drug reimbursement claims for Defendant's drug Ambien and Ambien CR – were false as that term is defined by the Federal False Claims Act in that they were ineligible for reimbursement as described herein.

203. For those records and/or statements that Defendant made or used or caused to be made or used, it was foreseeable and in fact the intended result that those statements and/or records would result in the payment of false reimbursement claims for Defendant's drug Ambien and Ambien CR. At all times relevant hereto, Defendant acted with the requisite scienter.

204. By reason of Defendant's unlawful practices, as aforesaid, substantial numbers of doctors, hospitals, pharmacies and other health care providers in the United States have been induced to prescribe and cause the purchase of substantial quantities of Defendant's drug Ambien and Ambien CR and thus provided substantial unlawful profits to Defendant. Moreover these purchases of Defendant's drug Ambien and Ambien CR occurred instead of purchases of less expensive drugs, procedures or treatment options for patients.

205. The amounts of the false or fraudulent claims caused to be paid pursuant to

Defendant's false records and statements made or used or caused to be made or used to the United States were material. Relator United States, being unaware of the falsity of the records and/or statements made or caused to be made by Defendant, and in reliance on the accuracy thereof, paid claims that Defendant knew to be false, as they intended.

206. It is believed that as a result of Defendant's violations of 31 U.S.C. § 3729 (a)(1)(B), the United States has suffered substantial losses in an amount that exceeds tens of millions of dollars, and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false record and/or statement made or used or caused to be made or used by Defendant.

207. Relators are private people with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to the Federal False Claims Act on behalf of themselves and the United States.

COUNT THREE

Violations of the Federal False Claims Act 31 U.S.C. § 3729(a)(2)(C) Conspiracy

208. Relators reallege and incorporate by reference each and every one of the foregoing paragraphs as if fully set forth herein.

209. This is a qui tam action brought by Relators and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. §3730 for Defendant's violations of 31 U.S.C. § 3729 et seq.

210. The Federal False Claims Act, 31 U.S.C. § 3729(a)(2)(C) provides:

> Liability for certain acts. Any person who—
>
> (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G); ...is liable to the United States Government for a civil penalty of not less than $ 5,500 and not more than $11,000, plus 3 times the amount of damages which the Government sustains because of the act of that person, ...

211. In violation of 31 U.S.C. § 3729(a)(2)(C), by the foregoing acts and omissions, Defendant conspired with physicians, paid consultants and others including but not limited to those physicians identified in this complaint to violate § 3729(a)(2)(A)(B) and (G) in violation of the False Claims Act, 31 U.S.C. § 3729(a)(2)(C).

212. By the foregoing acts and omissions, Defendant took actions in furtherance of their conspiracies, including but not limited to the payment of substantial sums of monies and/or illegal kickbacks to its co-conspirators as well as entering into unlawful contracts. Indeed, Defendant conspired to violate the Anti-kickback Statute 42 U.S.C. § 1328-7b(b) by unlawfully offering incentives to physicians and offering or receiving incentives from others that were in a position of authority to cause other physicians to write unnecessary prescriptions of Defendant's drug Ambien and Ambien CR, including for off-label uses. Said actions constitute violations of the Federal False Claims Act, 31 U.S.C. § 3729(a)(2)(C). Defendant committed other overt acts set forth above in furtherance of that conspiracy, all in violation of the laws of and causing damage to the United States.

213. As a consequence of Defendant's violations of 31 U.S.C. § 3729 (a)(2)(C), the United States has suffered substantial losses in an amount that exceeds tens of millions of dollars, and is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false claim Defendant conspired to get paid or allowed.

214. Relators are private people with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to the Federal False Claims Act on behalf of themselves and the United States.

COUNT FOUR

District of Columbia False Claims Act
D.C. Code Ann. § 2-331.02 et seq.

215. Relators restate and incorporate each and every allegation above as if the same were fully set forth herein.

216. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

217. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

218. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

219. By reason of the Defendant's acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

220. Pursuant to D.C. Code Ann. § 2-381.02, the District of Columbia is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT FIVE

California False Claims Act
Cal. Govt. Code §§ 12651 et seq.

221. Relators restate and incorporate each and every allegation above as if the same

were fully set forth herein.

222. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

223. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

224. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

225. By reason of the Defendant's acts, the State of California has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

226. Pursuant to Cal. Govt. Code § 12651(a), the State of California is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT SIX

Colorado Medicaid False Claims Act
Colo Rev. Stats. § 25.5-4-305 et seq.

227. Relators restate and incorporate each and every allegation above as if the same were fully set forth herein.

228. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Colorado State Government for payment or

approval.

229. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Colorado State Government to approve and pay such false and fraudulent claims.

230. The Colorado State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

231. By reason of the Defendant's acts, the State of Colorado has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

232. Pursuant to Colorado Revised Statutes § 25.5-4-305 et seq., the State of Colorado is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT SEVEN

Connecticut Medicaid False Claims Act
Conn. Gen. Stats. § 17b-301(a) et seq.

233. Relators restate and incorporate each and every allegation above as if the same were fully set forth herein.

234. This is a claim for treble damages and penalties under the Connecticut Medicaid False Claims Act, Conn. Gen. Stats. §§ 17b-301(a) et seq.

235. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, to an officer or employee of the State of Connecticut, false or fraudulent claims for payment or approval under medical assistance programs administered by the Department of

Social Services.

236. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to secure the payment or approval by the State of Connecticut of such false or fraudulent claims under medical assistance programs administered by the Department of Social Services.

237. By virtue of the acts described above, Defendant conspired with each other and with others to defraud the State of Connecticut by securing the allowance or payment of a false or fraudulent claim under medical assistance programs administered by the Department of Social Services.

238. The Connecticut State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

239. By reason of the Defendant's acts, the State of Connecticut has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

240. The State of Connecticut is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT EIGHT

Delaware False Claims and Reporting Act
Del. Code Ann. tit. 6, § 1201 et seq.

241. Relators restate and incorporate each and every allegation above as if the same were fully set forth herein.

242. By virtue of the acts described above, Defendant knowingly presented or caused

to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

243. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

244. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

245. By reason of the Defendant's acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

246. Pursuant to Del. Code Ann. tit. 6, § 1201(a), the State of Delaware is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT NINE

Florida False Claims Act
Fla. Stat. Ann. § 68.081 et seq.

247. Relators restate and incorporate each and every allegation above as if the same were fully set forth herein.

248. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

249. By virtue of the acts described above, Defendant knowingly made, used, or

caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

250. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

251. By reason of the Defendant's acts, the State of Florida has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

252. Pursuant to Fla. Stat. Ann. § 68.082(2), the State of Florida is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT TEN

Georgia False Medicaid Claims Act
Ga. Code. Ann. § 49-4-168.1 et seq.

253. Relators restate and incorporate each and every allegation above as if the same were fully set forth herein.

254. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

255. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

256. The Georgia State Government, unaware of the falsity of the records, statements

and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

257. By reason of the Defendant's acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

258. Pursuant to Ga. Code. Ann. § 49-4-168.1(a), the State of Georgia is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT ELEVEN

Hawaii False Claims Act
Haw. Rev. Stat. § 661-21 et seq.

259. Relators restate and incorporate each and every allegation above as if the same were fully set forth herein.

260. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

261. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

262. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

263. By reason of the Defendant's acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

264. Pursuant to Haw. Rev. Stat. § 661-21(a), the State of Hawaii is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT TWELVE

Illinois Whistleblower Reward and Protection Act
740 Ill. Comp. Stat. §§ 175/1 et seq.

265. Relators restate and incorporate each and every allegation above as if the same were fully set forth herein.

266. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

267. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

268. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendant as alleged herein.

269. By reason of the Defendant's acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

270. Pursuant to 740 Ill. Comp. Stat. § 175/3(a), the State of Illinois is entitled to three